NDA 19-872/S-009

McNeil Consumer Healthcare
Attention: Paula Oliver
Senior Director, Regulatory Compliance
7050 Camp Hill Road
Fort Washington, PA 19034-2299

JUL 25 2000

Dear Ms. Oliver:

Please refer to your supplemental new drug application dated December 8, 1998, received December 9, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol (acetaminophen) Extended Release Caplet, 650mg.

Please also refer to the Approvable letter that was issued for this supplemental new drug application on April 13, 2000. We acknowledge receipt of your submissions dated October 1, 1999, and April 24, July 5, and July 14,2000. Your submissions of July 5 and July 14, 2000 constitute a complete response to our April 13, 2000 action letter.

This supplemental new drug application provides for the following:

1. Change the product tradename to Tylenol Arthritis Pain;

2. Update the alcohol Warning to meeting the requirements of the Final Rule published October 23, 1998 (63 FR 56789); and

3. To change the company name to McNeil Consumer Healthcare.

We have completed the review of this supplemental new drug application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and “Drug Facts” format may render the product misbranded and an unapproved new drug.

As of the date of this letter there should be no further production of this drug product, intended for interstate commerce, that contains unapproved labeling.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar

material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-872/S-009." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit one copy of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. For administrative purposes, this submission should be sent to the NDA and should be identified as new correspondence to approved NDA 19-872.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Thomas A. Parmelee, Pharm.D., Regulatory Project Manager, at (301) 827-2271.

Sincerely,

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and. Research

Enclosure

APPROVED

JUL 25 2000

Drug Facts

Active ingredient (in each caplet) **Purpose**

Acetaminophen 650 mg ..... Pain reliever

Uses

temporarily relieves minor aches and pains due to:

- arthritis
- the common cold
- headache
- toothache
- muscular aches
- backache
- menstrual cramps

Warnings

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do not use

- with any other product containing acetaminophen

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Lasts up to 8 Hours

TYLENOL® ARTHRITIS PAIN

Acetaminophen Extended Release

FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

Extended Relief Caplets

100 Caplets–650 mg EACH* — ***Pain Reliever*** — **Capsule-Shaped Tablets*

XXXXXXX

Lasts up to 8 Hours

NDC 50580-TT12-10

TYLENOL® ARTHRITIS PAIN

Acetaminophen Extended Release

FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

Extended Relief Caplets

100 Caplets–650 mg EACH* — ***Pain Reliever*** — **Capsule-Shaped Tablets*

Lasts up to 8 Hours

TYLENOL® *Acetaminophen Extended Release*

ARTHRITIS PAIN

FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

Extended Relief Caplets

McNeil

McNeil Consumer Healthcare
DIVISION OF MCNEIL – PPC, INC.
FORT WASHINGTON, PA 19034 USA
www.tylenol.com

U.S. Pat. No. 4820522

Drug Facts (continued)

Directions ■ do not take more than directed

adults	■ take 2 caplets every 8 hours with water ■ swallow whole – do not crush, chew or dissolve ■ do not take more than 6 caplets in 24 hours ■ do not use for more than 10 days unless directed by a doctor
under 18 years of age	■ ask a doctor

Other information

- do not use if carton is opened or red neck wrap or foil inner seal imprinted with "Safety Seal®" is broken
- store at 20 - 25°C (68 - 77°F)
- avoid excessive heat at 40°C (104°F)
- see end panel for lot number and expiration date

Inactive ingredients

corn starch, hydroxyethyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions? Call 1-800-962-5357

What makes Tylenol® Arthritis Pain Extended Relief Caplets different?

- Uses a unique, patented bi-layer caplet. The first layer dissolves quickly to provide prompt relief while the second layer is time released to provide up to 8 hours of relief.
- For more information or questions, visit our website www.tylenol.com.
- The makers of Tylenol® do not manufacture store brands.

FPO

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FPO

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Warnings

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do not use ■ with any other product containing acetaminophen

Stop use and ask a doctor if ■ new symptoms occur ■ redness or swelling is present ■ pain gets worse or lasts for more than 10 days

If pregnant or breast-feeding, ask a health professional before use.

NDC 50580-112-10

Lasts up to 8 Hours

TYLENOL® ARTHRITIS PAIN

Acetaminophen Extended Release

FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

Extended Relief Caplets

Pain Reliever

100 Caplets–650 mg EACH* **Capsule-Shaped Tablets*

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Questions? Call 1-800-962-5357

EXP. DATE: CONTROL: XXXXXXX